SENATE ENROLLED ACT No. 41

AN ACT to amend the Indiana Code concerning insurance.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 5-10-8-17 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: **Sec. 17. (a) As used in this section, "covered individual" means an individual entitled to coverage under a state employee health plan.**

(b) As used in this section, "preceding prescription drug" means a prescription drug that, according to a step therapy protocol, must be:

(1) first used to treat a covered individual's condition; and

(2) as a result of the treatment under subdivision (1), determined to be inappropriate to treat the covered individual's condition;

as a condition of coverage under a state employee health plan for succeeding treatment with another prescription drug.

(c) As used in this section, "protocol exception" means a determination by a state employee health plan that, based on a review of a request for the determination and any supporting documentation:

(1) a step therapy protocol is not medically appropriate for treatment of a particular covered individual's condition; and

(2) the state employee health plan will:

(A) not require the covered individual's use of a preceding

prescription drug under the step therapy protocol; and

(B) provide immediate coverage for another prescription drug that is prescribed for the covered individual.

(d) As used in this section, "state employee health plan" refers to the following that provide coverage for prescription drugs:

(1) A self-insurance program established under section 7(b) of this chapter.

(2) A contract with a prepaid health care delivery plan that is entered into or renewed under section 7(c) of this chapter.

The term includes a person that administers prescription drug benefits on behalf of a state employee health plan.

(e) As used in this section, "step therapy protocol" means a protocol that specifies, as a condition of coverage under a state employee health plan, the order in which certain prescription drugs must be used to treat a covered individual's condition.

(f) As used in this section, "urgent care situation" means a covered individual's injury or condition about which the following apply:

(1) If medical care or treatment is not provided earlier than the time frame generally considered by the medical profession to be reasonable for a nonurgent situation, the injury or condition could seriously jeopardize the covered individual's:

(A) life or health; or

(B) ability to regain maximum function;

based on a prudent layperson's judgment.

(2) If medical care or treatment is not provided earlier than the time frame generally considered by the medical profession to be reasonable for a nonurgent situation, the injury or condition could subject the covered individual to severe pain that cannot be adequately managed, based on the covered individual's treating health care provider's judgment.

(g) A state employee health plan shall publish on the state employee health plan's Internet web site, and provide to a covered individual in writing, a procedure for the covered individual's use in requesting a protocol exception. The procedure must include the following provisions:

(1) A description of the manner in which a covered individual may request a protocol exception.

(2) That the state employee health plan shall make a determination concerning a protocol exception request, or an appeal of a denial of a protocol exception request, not more than:

(A) in an urgent care situation, one (1) business day after receiving the request or appeal; or

(B) in a nonurgent care situation, three (3) business days after receiving the request or appeal.

(3) That a protocol exception will be granted if any of the following apply:

(A) A preceding prescription drug is contraindicated or will likely cause an adverse reaction or physical or mental harm to the covered individual.

(B) A preceding prescription drug is expected to be ineffective, based on both of the following:

(i) The known clinical characteristics of the covered individual.

(ii) Known characteristics of the preceding prescription drug, as found in sound clinical evidence.

(C) The covered individual has previously received:

(i) a preceding prescription drug; or

(ii) another prescription drug that is in the same pharmacologic class or has the same mechanism of action as a preceding prescription drug;

and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

(D) Based on clinical appropriateness, a preceding prescription drug is not in the best interest of the covered individual because the covered individual's use of the preceding prescription drug is expected to:

(i) cause a significant barrier to the covered individual's adherence to or compliance with the covered individual's plan of care;

(ii) worsen a comorbid condition of the covered individual; or

(iii) decrease the covered individual's ability to achieve or maintain reasonable functional ability in performing daily activities.

(4) That when a protocol exception is granted, the state employee health plan shall notify the covered individual and the covered individual's health care provider of the authorization for coverage of the prescription drug that is the subject of the protocol exception.

(5) That if:

(A) a protocol exception request; or

(B) an appeal of a denied protocol exception request;

results in a denial of the protocol exception, the state employee health plan shall provide to the covered individual and the treating health care provider notice of the denial, including a detailed, written explanation of the reason for the denial and the clinical rationale that supports the denial.

(6) That the state employee health plan may request a copy of relevant documentation from the covered individual's medical record in support of a protocol exception.

SECTION 2. IC 5-10-8-18 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: **Sec. 18. (a) The definitions in section 17 of this chapter apply throughout this section.**

(b) This section applies to a state employee health plan that uses a formulary, cost sharing, or utilization review for prescription drug coverage.

(c) A state employee health plan shall not remove a prescription drug from the state employee health plan's formulary, change the cost sharing requirements that apply to a prescription drug, or change the utilization review requirements that apply to a prescription drug unless the state employee health plan does at least one (1) of the following:

(1) At least sixty (60) days before the removal or change is effective, send written notice of the removal or change to each covered individual for whom the prescription drug has been prescribed during the preceding twelve (12) month period.

(2) At the time a covered individual for whom the prescription drug has been prescribed during the preceding twelve (12) month period requests a refill of the prescription drug, provide to the covered individual:

(A) written notice of the removal or change; and

(B) a sixty (60) day supply of the prescription drug under the terms that applied before the removal or change.

SECTION 3. IC 27-8-5-30 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: **Sec. 30. (a) As used in this section, "insured" means an individual who is entitled to coverage under a policy of accident and sickness insurance.**

(b) As used in this section, "insurer" refers to an insurer that issues a policy of accident and sickness insurance. The term includes a person that administers prescription drug benefits on behalf of an insurer.

(c) As used in this section, "policy of accident and sickness insurance" means a policy of accident and sickness insurance that provides coverage for prescription drugs.

(d) As used in this section, "preceding prescription drug" means a prescription drug that, according to a step therapy protocol, must be:

(1) first used to treat an insured's condition; and

(2) as a result of the treatment under subdivision (1), determined to be inappropriate to treat the insured's condition;

as a condition of coverage under a policy of accident and sickness insurance for succeeding treatment with another prescription drug.

(e) As used in this section, "protocol exception" means a determination by an insurer that, based on a review of a request for the determination and any supporting documentation:

(1) a step therapy protocol is not medically appropriate for treatment of a particular insured's condition; and

(2) the insurer will:

(A) not require the insured's use of a preceding prescription drug under the step therapy protocol; and

(B) provide immediate coverage for another prescription drug that is prescribed for the insured.

(f) As used in this section, "step therapy protocol" means a protocol that specifies, as a condition of coverage under a policy of accident and sickness insurance, the order in which certain prescription drugs must be used to treat an insured's condition.

(g) As used in this section, "urgent care situation" means an insured's injury or condition about which the following apply:

(1) If medical care or treatment is not provided earlier than the time frame generally considered by the medical profession to be reasonable for a nonurgent situation, the injury or condition could seriously jeopardize the insured's:

(A) life or health; or

(B) ability to regain maximum function;

based on a prudent layperson's judgment.

(2) If medical care or treatment is not provided earlier than the time frame generally considered by the medical profession to be reasonable for a nonurgent situation, the injury or condition could subject the insured to severe pain that cannot be adequately managed, based on the insured's treating health care provider's judgment.

(h) An insurer shall publish on the insurer's Internet web site, and provide to an insured in writing, a procedure for the insured's use in requesting a protocol exception. The procedure must include the following provisions:

(1) A description of the manner in which an insured may request a protocol exception.

(2) That the insurer shall make a determination concerning a protocol exception request, or an appeal of a denial of a protocol exception request, not more than:

(A) in an urgent care situation, one (1) business day after receiving the request or appeal; or

(B) in a nonurgent care situation, three (3) business days after receiving the request or appeal.

(3) That a protocol exception will be granted if any of the following apply:

(A) A preceding prescription drug is contraindicated or will likely cause an adverse reaction or physical or mental harm to the insured.

(B) A preceding prescription drug is expected to be ineffective, based on both of the following:

(i) The known clinical characteristics of the insured.

(ii) Known characteristics of the preceding prescription drug, as found in sound clinical evidence.

(C) The insured has previously received:

(i) a preceding prescription drug; or

(ii) another prescription drug that is in the same pharmacologic class or has the same mechanism of action as a preceding prescription drug;

and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

(D) Based on clinical appropriateness, a preceding prescription drug is not in the best interest of the insured because the insured's use of the preceding prescription drug is expected to:

(i) cause a significant barrier to the insured's adherence to or compliance with the insured's plan of care;

(ii) worsen a comorbid condition of the insured; or

(iii) decrease the insured's ability to achieve or maintain reasonable functional ability in performing daily activities.

(4) That when a protocol exception is granted, the insurer

shall notify the insured and the insured's health care provider of the authorization for coverage of the prescription drug that is the subject of the protocol exception.

(5) That if:

(A) a protocol exception request; or

(B) an appeal of a denied protocol exception request;

results in a denial of the protocol exception, the insurer shall provide to the insured and the treating health care provider notice of the denial, including a detailed, written explanation of the reason for the denial and the clinical rationale that supports the denial.

(6) That the insurer may request a copy of relevant documentation from the insured's medical record in support of a protocol exception.

SECTION 4. IC 27-8-5-31 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: **Sec. 31. (a) The definitions in section 30 of this chapter apply throughout this section.**

(b) This section applies to an insurer that uses a formulary, cost sharing, or utilization review for prescription drug coverage.

(c) An insurer shall not remove a prescription drug from the insurer's formulary, change the cost sharing requirements that apply to a prescription drug, or change the utilization review requirements that apply to a prescription drug unless the insurer does at least one (1) of the following:

(1) At least sixty (60) days before the removal or change is effective, send written notice of the removal or change to each insured for whom the prescription drug has been prescribed during the preceding twelve (12) month period.

(2) At the time an insured for whom the prescription drug has been prescribed during the preceding twelve (12) month period requests a refill of the prescription drug, provide to the insured:

(A) written notice of the removal or change; and

(B) a sixty (60) day supply of the prescription drug under the terms that applied before the removal or change.

SECTION 5. IC 27-13-7-23 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: **Sec. 23. (a) As used in this section, "group contract" refers to a group contract that provides coverage for prescription drugs.**

(b) As used in this section, "health maintenance organization"

refers to a health maintenance organization that provides coverage for prescription drugs. The term includes the following:

(1) A limited service health maintenance organization.

(2) A person that administers prescription drug benefits on behalf of a health maintenance organization or a limited service health maintenance organization.

(c) As used in this section, "individual contract" refers to an individual contract that provides coverage for prescription drugs.

(d) As used in this section, "preceding prescription drug" means a prescription drug that, according to a step therapy protocol, must be:

(1) first used to treat an enrollee's condition; and

(2) as a result of the treatment under subdivision (1), determined to be inappropriate to treat the enrollee's condition;

as a condition of coverage under an individual contract or a group contract for succeeding treatment with another prescription drug.

(e) As used in this section, "protocol exception" means a determination by a health maintenance organization that, based on a review of a request for the determination and any supporting documentation:

(1) a step therapy protocol is not medically appropriate for treatment of a particular enrollee's condition; and

(2) the health maintenance organization will:

(A) not require the enrollee's use of a preceding prescription drug under the step therapy protocol; and

(B) provide immediate coverage for another prescription drug that is prescribed for the enrollee.

(f) As used in this section, "step therapy protocol" means a protocol that specifies, as a condition of coverage under an individual contract or a group contract, the order in which certain prescription drugs must be used to treat an enrollee's condition.

(g) As used in this section, "urgent care situation" means an enrollee's injury or condition about which the following apply:

(1) If medical care or treatment is not provided earlier than the time frame generally considered by the medical profession to be reasonable for a nonurgent situation, the injury or condition could seriously jeopardize the enrollee's:

(A) life or health; or

(B) ability to regain maximum function;

based on a prudent layperson's judgment.

(2) If medical care or treatment is not provided earlier than

the time frame generally considered by the medical profession to be reasonable for a nonurgent situation, the injury or condition could subject the enrollee to severe pain that cannot be adequately managed, based on the enrollee's treating health care provider's judgment.

(h) A health maintenance organization shall publish on the health maintenance organization's Internet web site, and provide to an enrollee in writing, a procedure for the enrollee's use in requesting a protocol exception. The procedure must include the following provisions:

(1) A description of the manner in which an enrollee may request a protocol exception.

(2) That the health maintenance organization shall make a determination concerning a protocol exception request, or an appeal of a denial of a protocol exception request, not more than:

(A) in an urgent care situation, one (1) business day after receiving the request or appeal; or

(B) in a nonurgent care situation, three (3) business days after receiving the request or appeal.

(3) That a protocol exception will be granted if any of the following apply:

(A) A preceding prescription drug is contraindicated or will likely cause an adverse reaction or physical or mental harm to the enrollee.

(B) A preceding prescription drug is expected to be ineffective, based on both of the following:

(i) The known clinical characteristics of the enrollee.

(ii) Known characteristics of the preceding prescription drug, as found in sound clinical evidence.

(C) The enrollee has previously received:

(i) a preceding prescription drug; or

(ii) another prescription drug that is in the same pharmacologic class or has the same mechanism of action as a preceding prescription drug;

and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

(D) Based on clinical appropriateness, a preceding prescription drug is not in the best interest of the enrollee because the enrollee's use of the preceding prescription drug is expected to:

(i) cause a significant barrier to the enrollee's adherence to or compliance with the enrollee's plan of care;

(ii) worsen a comorbid condition of the enrollee; or

(iii) decrease the enrollee's ability to achieve or maintain reasonable functional ability in performing daily activities.

(4) That when a protocol exception is granted, the health maintenance organization shall notify the enrollee and the enrollee's health care provider of the authorization for coverage of the prescription drug that is the subject of the protocol exception.

(5) That if:

(A) a protocol exception request; or

(B) an appeal of a denied protocol exception request;

results in a denial of the protocol exception, the health maintenance organization shall provide to the enrollee and the treating health care provider notice of the denial, including a detailed, written explanation of the reason for the denial and the clinical rationale that supports the denial.

(6) That the insurer may request a copy of relevant documentation from the insured's medical record in support of a protocol exception.

SECTION 6. IC 27-13-38-7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: **Sec. 7. (a) The definitions in IC 27-13-7-23 apply throughout this section.**

(b) A health maintenance organization shall not remove a prescription drug from the health maintenance organization's formulary, change the cost sharing requirements that apply to a prescription drug, or change the utilization review program requirements that apply to a prescription drug unless that health maintenance organization does at least one (1) of the following:

(1) At least sixty (60) days before the removal or change is effective, send written notice of the removal or change to each enrollee for whom the prescription drug has been prescribed during the preceding twelve (12) month period.

(2) At the time an enrollee for whom the prescription drug has been prescribed during the preceding twelve (12) month period requests a refill of the prescription drug, provide to the enrollee:

(A) written notice of the removal or change; and

(B) a sixty (60) day supply of the prescription drug under

the terms that applied before the removal or change.

President of the Senate

President Pro Tempore

Speaker of the House of Representatives

Governor of the State of Indiana

Date: _____ Time: _____